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INSIDE THIS ISSUE

Approval: Barr gets thumbs up for generic cancer drug.....Page 2

Regulatory Affairs: FDA advises companies on Subpart H approval.....Page 3

Manufacturing: OGD provides clarification on USP rulePage 5

Antitrust: Barr antitrust cases to continue.....Page 6

Ask the Expert: Chad Landmon discusses *Prasco LLC v. Medicis Pharm Corp.*.....Page 7

Lawsuits: Hi-Tech Sues FDA..... Page 8

Patent Suits: Firms settle in Astelin casePage 9

Apotex, Impax lose in Prilosec case.....Page 9

Barr faces suit over Faza-Clo drug.....Page 9

International: Pfizer gets win over firm in Danish Lipitor case.....Page 10

OIG: CMS Should Explore Options To Address Price Discrepancies

The Medicare payment for the colon cancer drug irinotecan was more than double the calculated average manufacturer sales price in March, despite the availability of generic alternatives, a report by HHS' Office of Inspector General (OIG) said.

The OIG recommends that the Centers for Medicare & Medicaid Services (CMS) explore options to expedite the process to ensure that Medicare payment amounts for drugs with newly available generic versions accurately reflect market prices. If the OIG finds that an average sales price exceeds the widely available market price or average manufacturing price by 5 percent, the HHS secretary may disregard the average sales price when setting reimbursement. However, CMS has yet to make any changes as a result of the pricing comparisons.

(See **CMS**, Page 2)

FDA Warns Sandoz on Production Of Generic Toprol XL

The FDA is questioning a decision by Novartis subsidiary Sandoz to continue distributing generic versions of Toprol XL when the company did not adequately validate its production process.

“We question the continued distribution of this product until better process controls are implemented and process validation is completed,” the FDA tells Sandoz in a warning letter posted on its website Aug. 26.

“You originally decided to temporarily suspend distribution of metoprolol 25- and 50-mg tablets [generic Toprol XL] until the available pre-compression and dissolution data was reviewed,” the FDA says in the Aug. 12 letter. “However, you have decided to resume distribution of these products based on your rationale that successful, routine, finished-product testing of manufactured lots is sufficient proof that the product is of acceptable quality.”

(See **Sandoz**, Page 4)

Barr Gets Approval for Generic Cancer Drug

Barr Pharmaceuticals' subsidiary Pliva-Lachema has received final approval from the FDA to market its generic version of Pfizer's myeloma drug Aredia.

The approval covers pamidronate disodium in injectable doses of 30, 60 and 90 mg/mL. Barr plans to start marketing the product in the fourth quarter of this year, the company said.

Total annual sales in the pamidronate disodium injection market were roughly \$21 million in the 12 months that ended in June, Barr said, citing sales data from pharmaceutical market research firm IMS Health.

With this approval, Barr's U.S. generic injectable-drug portfolio is comprised of eight products.

According to the Multiple Myeloma Research Foundation, Aredia is one of a group of compounds called bisphosphonates that are used to treat myeloma bone disease. They help reduce the progression of bone disease, decrease bone pain and reduce fractures.

Earlier this year, the FDA issued a Med-Watch alert for the risk of severe and sometimes incapacitating bone, joint or muscle pain in patients taking bisphosphonates.

Bisphosphonates on the market include Merck's Fosamax (alendronate sodium), Roche's Boniva (ibandronate sodium) and Aredia.

— Martin Gidron

CMS, from Page 1

The FDA approved the first generic version of Pfizer's chemotherapy agent Camptosar (irinotecan HCl) Feb. 20. Nine manufacturers have received approval for generic forms of the drug, which can be sold at substantial discounts compared with the branded price.

The inspector general's office found that the Medicare payment for irinotecan was \$126.31, more than double the OIG-calculated average manufacturer sales price of \$51.59, according to the report.

It also estimates that if the Medicare payment amount for irinotecan had been based on the average manufacturer sales price in March, spending on the drug would have been reduced by \$6.5 million.

Because of a two-quarter lag, the Medicare payment for brand and generic irinotecan will be based on the brand average sales prices. The payment amount will not include the generic average sales price until the third quarter, according to the report.

In a letter to HHS, CMS says it "remains committed to ensuring accurate payments for drug products under the [average sales price] methodology and continuously looks for ways to refine and improve the methods we use."

— Elizabeth Jones

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Agency Mulling Withdrawal of Speedier Midodrine HCl Approval

The FDA has informed companies holding applications for midodrine HCl that they must obtain approval of postmarketing studies verifying the clinical benefit of their product or the agency will initiate proceedings to withdraw approval of the applications.

Midodrine HCl is the generic version of Shire's Proamatine, which is indicated to treat symptomatic orthostatic hypotension.

Proamatine was approved Sept. 6, 1996, under the FDA's accelerated approval regulations in 21 CFR part 314, Subpart H.

The drug's approval was based on a surrogate endpoint that requires the sponsor to complete postmarketing studies to verify the efficacy of the drug.

Shire has not received FDA approval to conduct such a study.

FDA Outlines Requirements

In an Aug. 18 letter, the agency informs midodrine application holders of the potential for three-year exclusivity if they submit an application or supplement containing new studies other than bioavailability research to verify the clinical benefit of the drug.

Companies will be considered to have conducted or sponsored the investigations in support of the three-year exclusivity period if they provided "substantial support" for the studies.

To show it met that requirement, a company must submit a certified public accountant's statement that it provided "50 percent or more of the cost of conducting the study or an explanation of why FDA should consider [it] to have conducted or sponsored the study if [its] financial contribution is less than 50 percent or [it] did not sponsor the investigational new drug," according to the agency's letter.

The FDA issued a request in August 2007 for comment concerning the availability of this exclusivity. Upsher-Smith, Mylan Pharmaceuticals, Impax Laboratories, Sandoz and Apotex responded to the request. The firms were considering whether to collaborate to complete the studies necessary to demonstrate the efficacy of the drug, according to the responses to the FDA.

The agency also warns application holders in its recent letter that it will issue a notice of opportunity for a hearing on a proposal to withdraw approval of the midodrine HCl for their NDAs and ANDAs if they do not obtain approval for an application or supplement containing studies that verify clinical benefit for the product.

Shire Continues Work With FDA

"Shire continues to work with the FDA and other pharmaceutical companies concerning details associated with the clinical benefits of Proamatine (midodrine HCl) in order to allow patients whose lives are enhanced by this medicine to continue to receive it," Shire spokesman Matt Cabrey said.

Under Subpart H, Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, the FDA may withdraw approval of such drugs if:

- The applicant fails to perform the required postmarketing study with due diligence;
- A postmarketing clinical study fails to verify clinical benefit;
- Use after marketing demonstrates that postmarketing restrictions are inadequate to assure safe use of the drug;
- The applicant fails to adhere to agreed postmarketing restrictions;
- The promotional materials are false or misleading; or
- Other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

— Elizabeth Jones

Sandoz, from Page 1

The company manufactures metoprolol succinate at its facility in Wilson, N.C. The warning letter resulted from inspection findings in March.

Sandoz continues to collaborate with the FDA to promptly resolve the agency's concerns and says all products released and distributed met all specifications, according to a written statement about the warning letter.

Par Pharmaceutical distributes the authorized generic of Toprol XL (metoprolol succinate), which is manufactured by AstraZeneca. Sandoz and KV Pharmaceutical market the two other generics. The drug is a beta blocker indicated to treat hypertension, angina and heart failure. It was a blockbuster medication before it went generic.

According to the letter, there were failures in process validation studies for the 50-mg dose of the drug. One validation lot failed content uniformity at high-speed compression while another failed dissolution at high hardness for the four-hour time point.

In response to the process validation failures, Sandoz obtained additional samples from other commercial lots unrelated to the validation study, using one conforming validation lot and two unrelated commercial lots to deem the process acceptable, the FDA says.

Concerns About Other Sites

"It is not acceptable to disregard the findings in one of the lots by stating that another lot made under the same process had sample results that met the criteria. To the contrary, this is an indication that you have not identified, and are unable to control, those factors that cause variability in the process," the FDA letter says. "This also indicates that you lack a robust process design. Consequently, you do not have a high level of assurance that the process is in a state of control and is capable of consistently producing a product that meets specifications."

The issues affecting the firm's validation of the metoprolol manufacturing process are a

potential indicator of problems with other Sandoz drugs, the letter says.

"We are ... concerned that you may not be utilizing a global approach to the implementation of manufacturing controls. For example, one proposed corrective action at the Wilson site is to implement an automated investigation management tracking system (Trackwise), which is already in use at other Sandoz sites.

"It is our expectation that all Sandoz sites intended to be used for the manufacture of drugs have a comprehensive evaluation to assure compliance with all laws and regulations governing the manufacture of drugs. We request that you provide documentation describing the specific steps you will take to perform these evaluations and to implement the necessary corrective actions at all Sandoz sites," the FDA tells the company.

Investigations

The company also was cited for failing to investigate or complete reviews on time of multiple products made at the Wilson site.

Sandoz's policy is to complete investigations into failures within 30 days and require a report on any delays in that process. However, numerous investigations were not initiated or completed until the FDA started its inspection, and the reports explaining investigation delays were not on file, the letter says.

Investigations for 18 rejected lots of generic Toprol XL were not conducted, the letter says. They were initiated after the FDA inspection.

Other investigations — including one for failing dissolution results for the muscle relaxant orphenadrine citrate — were not completed until one year after the failures.

Sandoz did not complete investigations on time, as its standard operating procedure requires, for at least 15 products including the hypertension

(See **Sandoz, Page 5**)

OGD Issues Clarification on USP Residual Solvents Rule

The Office of Generic Drugs (OGD) has issued a clarification identifying the information that will be considered acceptable for demonstrating compliance with a U.S. Pharmacopeia (USP) standard for controlling residual solvents that took effect July 1.

The clarification comes after attempts at implementation of <467> resulted in variability in the information being submitted. OGD hopes to resolve uncertainty regarding what information would be considered satisfactory for demonstrating compliance with the chapter.

New applications and pending original applications that do not demonstrate compliance with USP <467> will be considered deficient. Also, all supplements and amendments submitted that require an acceptable drug product specification or certificate of analysis for approval that do not demonstrate compliance will be considered deficient.

An applicant must verify vendor statements or certificates of analysis (COA) stating that the USP <467> standard has been met except when the statement says certain solvents have not been used and are assumed not to have been designated as Class 1, 2 or 3.

Class 1 solvents, products and excipients should not be used in the manufacturing of drug substances because of their toxicity or effect on the environment. Class 2 solvents should be limited in pharmaceutical products because of toxicity. Solvents in Class 3 are considered risky for humans. However, there are no long-term toxicity or carcinogenicity studies for many of the solvents.

An applicant's commitment to meet USP <467> does not demonstrate compliance except when applications are otherwise acceptable for tentative approval. In those cases, applicants must demonstrate compliance before final approval.

In the case of President's Emergency Plan for AIDS Relief products, tentative approval may be granted if there is a commitment to demonstrate

compliance within six months. This extension reflects the critical role of these products in treatment of a significant medical emergency.

OGD will consider an application to be complete if it contains the following information for each ingredient used in the formulation:

- Manufacturer's COA listing all solvents used in the manufacture of the ingredient or a statement that no solvents are used in the manufacture;

(See OGD, Page 10)

Sandoz, from Page 4

drug lisinopril, painkiller fentanyl citrate lozenges and sedative-hypnotic drug alprazolam.

Audit Trails

The company also was cited for not having a laboratory computer system that tracked the deletion of raw data or files.

According to the letter, the firm uses the Agilent Chemstation data acquisition system for the HP 8453 UV/Visible spectrophotometer, which is used for dissolution testing of finished product, stability samples and process- and method-validation studies.

The system allows Sandoz analysts to modify, overwrite and delete original data files without leaving an audit trail, the letter says.

"Your laboratory computer system lacks necessary controls to ensure that data is protected from tampering, and it also lacks audit trail capabilities to detect data that could be potentially compromised," the FDA says.

The company would not say whether it plans to recall any products made at its Wilson facility and would not confirm whether it has any pending ANDAs referencing the site.

The warning letter can be accessed at www.fda.gov/foi/warning_letters/s6891c.pdf.

— Christopher Hollis

Generic Ovcon Antitrust Cases to Proceed

A federal district court judge has ruled that three antitrust cases against Barr Pharmaceuticals filed by direct purchasers cannot be decided on summary judgment.

Meijer, Walgreen and CVS Pharmacy filed the suit in the U.S. District Court for the District of Columbia claiming that Barr and Warner Chilcott made an illegal agreement to delay the introduction of generic Ovcon (ethinyl estradiol/norethindrone) in 2004.

The companies also sued Warner Chilcott in the same court. However, the judge in the case approved a settlement in July, leaving Barr as the sole defendant.

Under that agreement, Barr would not sell its product for five years and would be obligated to supply Warner Chilcott with the drug for the same period.

Barr maintained that the agreement favored competition and consumers, including a safe, stable and reliable supply of a product that could continue to compete aggressively against other hormone contraceptives in the marketplace.

The court ruled the agreement between Barr and Warner Chilcott cannot be condemned as per se unlawful restraint of trade. Furthermore, it could not resolve the definition of the disputed market on summary judgment. A status hearing in the case will be held Sept. 17.

Warner Chilcott purchased Ovcon from Bristol-Myers Squibb in 2000. The drug had sales of \$4 million for the second quarter, according to Warner Chilcott.

Earlier this year, dozens of states and the District of Columbia settled an antitrust lawsuit against Barr Pharmaceuticals over allegations that the firm kept generic Ovcon off the market, with Barr agreeing to pay a total of \$5.9 million (*Generic Line*, March 5). — Elizabeth Jones

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 A close-up photograph of a glass test tube held in a metal clamp, being filled with a vibrant green liquid from a glass flask. The background is blurred, focusing attention on the liquid transfer.

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ASK THE EXPERT

Recently, the U.S. Court of Appeals for the Federal Circuit issued its decision in *Prasco LLC v. Medicis Pharm Corp.*, potentially halting the trend of liberalizing the declaratory judgment jurisdiction standard. *Generic Line* asked Chad Landmon, a partner with the law firm Axinn, Veltrap & Harkrider LLP, to explain the ruling and what companies can learn from it. He also discusses the ongoing implications from two declaratory judgment cases from last year.

Could you explain the January 2007 Supreme Court MedImmune ruling?

Landmon: On its surface, the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, held that a patent licensee may bring a declaratory judgment action seeking a decision that the licensed patent is invalid or not infringed even if the licensee is continuing to pay royalties under the license. With little fanfare and minimal discussion, however, the Supreme Court disposed of the Federal Circuit's "reasonable apprehension of suit" test, which had been applied for decades to evaluate whether a court has subject matter jurisdiction over a declaratory judgment complaint.

In fact, the Court noted its disapproval of this decades-old test with little more than a footnote. Simply stated, the Court found that the test was inconsistent with Supreme Court precedent, including, among other cases, *Altvater v. Freeman* (1943).

The Court did not set forth an alternative test specific to patent cases. Instead, the Court recognized that its precedent has not always drawn "the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not." Quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.* (1941), the Court generally summarized the standard as follows:

Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy,

between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

How have subsequent decisions relaxed the declaratory judgment jurisdiction standard?

Landmon: Later in 2007, in *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, the Federal Circuit confirmed that *MedImmune* had, in fact, overruled the reasonable apprehension of suit test. In *Teva*, the Federal Circuit found a justiciable controversy where several patents were listed in the Orange Book, but the brand company brought suit on only one of the patents.

Earlier this year, the Federal Circuit went a step further in the pharmaceutical context in *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.* In that decision, the court determined that a generic drug applicant could bring a declaratory judgment action to challenge a brand company's patent even after the brand company granted a covenant not to sue. Specifically, the court held that an actual and justiciable controversy existed as to the generic applicant's right to come to market because the patent at issue was listed in the FDA's Orange Book and was the basis for an earlier generic applicant's 180-day generic marketing exclusivity period under the Hatch-Waxman regulatory regime.

Could you explain the Prasco LLC v. Medicis Pharm Corp. decision and what impact it could have on future patent infringement cases?

Landmon: In *Prasco*, the Federal Circuit may have halted the trend of liberalizing the declaratory judgment jurisdiction standard. In this case, the patent holder had marked its product with four patent numbers. In addition, the patent holder had sued Prasco and other defendants in the past for patent infringement based upon unrelated patents and products. Before launching its product, Prasco filed the declaratory judgment

(See **Expert**, Page 8)

Expert, from Page 7

action, seeking a declaration that its product did not infringe the patents at issue. Prasco also sent a product sample to the patent holder and requested a covenant not to sue. The patent holder refused to grant the covenant not to sue, and Prasco launched its product onto the market.

Considering the totality of the circumstances, the Federal Circuit determined that there was no controversy of sufficient “immediacy and reality” to support jurisdiction. The court held that the mere existence of the patents and the patent marking by the patent holder was not enough to create jurisdiction. The court also minimized Prasco’s alleged “paralyzing uncertainty” from the risk of being sued by the patent holder, noting that such an allegation was undercut by Prasco’s decision to launch its product.

Addressing *MedImmune*, the court reasoned:

Although *MedImmune* clarified that an injury-in-fact sufficient to create an actual controversy can exist even when there is no apprehension of suit, it did not change the bedrock rule that a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is caused by the defendants — an objective standard that cannot be met by a purely subjective or speculative fear of future harm.

Because the patent holder had not taken any position adverse to Prasco and had not interfered with its right to market its product, the court concluded that there was no jurisdiction to maintain the declaratory judgment action.

The decision in *Prasco* may signal another shift in the pendulum of declaratory judgment law. In bringing a declaratory judgment action, a potential infringer may now have to jump through some additional hoops in order to get the court to recognize jurisdiction in the case.

What does this mean for generic firms?

Landmon: Interestingly, in rendering its decision in *Prasco*, the Federal Circuit implied that the

situation would be different for generic pharmaceutical products that are governed by the Hatch-Waxman regulatory regime. Citing its decision in *Caraco*, the court noted that the mere existence of a patent, which may be listed by the brand company in the FDA’s Orange Book, can create a regulatory barrier to approval of the generic company’s proposed product. As a result, the Federal Circuit may have left the window open for generic pharmaceutical companies to continue to bring declaratory judgment actions merely based upon a brand pharmaceutical company listing a patent in the FDA’s Orange Book. Only time will tell how the courts may apply *Prasco* in declaratory judgment actions filed by generic companies.

Hi-Tech Brings Suit to Confirm Exclusivity of Generic Cosopt

Hi-Tech Pharmacal has filed a complaint against the FDA requesting a declaratory judgment related to the company’s ANDA for a generic version of Merck’s Cosopt, a glaucoma treatment.

The company brought its case for generic Cosopt (dorzolamide HCl/timolol maleate) in the U.S. District Court for the District of Columbia. It seeks confirmation that it is entitled to a 180-day period of market exclusivity as the first applicant to submit an ANDA containing a Paragraph IV certification challenging the validity of the brand company’s patents, according to Hi-Tech.

The company submitted its ANDA in 2005 and won tentative approval April 10, according to the court filing. Apotex won tentative approval from the FDA in July for its generic version of Cosopt.

Hi-Tech planned to begin marketing the product upon the completion of Merck’s pediatric exclusivity period Oct. 28. The FDA has postponed a decision on exclusivity until that date. Hi-Tech’s complaint seeks an injunction preventing the FDA from granting final marketing approval to any other ANDA for 180 days after Hi-Tech begins selling the product.

Merck’s Cosopt had sales of \$334 million in 2007, according to IMS. — Elizabeth Jones

Meda, Cobalt Settle In Astelin Case

The Swedish drug company Meda Pharmaceuticals has settled its U.S. patent infringement lawsuit against the Canadian drug company Cobalt Pharmaceuticals.

Under the terms of the settlement, Cobalt admits infringing on Meda's patent for its allergic and nonallergic rhinitis drug Astelin (azelastine HCl) nasal spray by filing an ANDA for a generic version of the drug in July 2007, Meda said.

In exchange, Cobalt gets permission to launch a generic version of Astelin under a license from Meda no earlier than Aug. 28, 2010. If it chooses to do so, Cobalt will pay 32.5 percent of its net sales of the product to Meda until Feb. 1, 2011. The deal must be approved by the FTC and the Justice Department.

Meda's U.S. patent for the drug expires Nov. 1, 2010, with pediatric exclusivity lasting until May 1, 2011.

"With this settlement agreement, Meda has no further patent litigations pending in the U.S. for Astelin," Anders Lonner, CEO of Meda, said. — Martin Gidron

AstraZeneca Wins Prilosec Appeals Case

A federal appeals court has affirmed a district court's decision that Apotex and Impax infringed on patents covering AstraZeneca's heartburn drug Prilosec.

In its complaint, AstraZeneca alleges the defendants had infringed on the '505 and '230 patents relating to the active ingredient in Prilosec (omeprazole), according to court documents. The companies were two of several firms to file ANDAs for the drug.

Impax sought approval to sell a generic version of Prilosec in 10- and 20-mg doses in December 1999, prompting AstraZeneca to file suit

in the U.S. District Court for the Southern District of New York. The generic firm later amended its ANDA to include the 40-mg version. Apotex also filed an ANDA for the three strengths of the drug.

The district court consolidated several of the Prilosec cases and heard arguments in a 42-day bench trial. The court found for AstraZeneca, rejecting the defendants' arguments for making the effective date of their ANDAs earlier than Oct. 20, 2007. The patents had expired April 20, 2007.

The appeals court ruling comes roughly two months after the same court upheld a decision by the U.S. District Court for the Southern District of New York finding that Mylan and Esteve did not infringe on the same patents.

— Elizabeth Jones

Barr Sued Over Generic FazaClo

Barr Laboratories is facing a lawsuit for challenging patents covering the antipsychotic FazaClo 25- and 100-mg tablets.

Cima Labs, Azur Pharma Limited and Azur Pharma International III Limited are suing Barr in the U.S. District Court for the District of Delaware after receiving notice that Barr planned to make a generic version of FazaClo (clozapine) before Cima's '392 and '981 patents expire in April 2018.

Azur Pharma is the exclusive licensee of the patents in the U.S. Cima manufactures the product for Azur, while Azur International holds the FazaClo NDA.

Both patents are being reexamined by the Patent & Trademark Office (PTO), which means they could be found completely invalid or their claims significantly amended. "If the patents are invalidated, the case against Barr will be dismissed because they technically will no longer exist. If the claims are somehow

(See **FazaClo**, Page 10)

Danish Court Finds for Pfizer in Lipitor Dispute

Denmark's Eastern High Court has ruled in Pfizer's favor against generics company Ranbaxy in challenges to two of its patents on atorvastatin, Lipitor's active ingredient.

The court has found that the '588 Danish patent, which expires in November 2011, would be infringed by Ranbaxy's generic Lipitor (atorvastatin calcium) product. The court also held that the '281 European patent, which expires in July 2010, is valid. The decision prevents Ranbaxy from launching its generic product before November 2011.

"Today's decision is an important outcome for Pfizer and other medical innovators who invest in high-risk research to develop life-saving medicines for millions of patients," Pfizer's Denmark Country Manager Karin Verland says in a statement.

In June, Pfizer settled most of its global patent disputes with Ranbaxy. Under an agreement, Ranbaxy will be licensed to sell generic Lipitor and Caduet, which combines Lipitor with Pfizer's hypertension drug Norvasc (amlodipine besylate), in the U.S. starting Nov. 30, 2011. Ranbaxy also will be allowed to sell generic Lipitor starting various dates in Canada, Belgium, the Netherlands, Germany, Sweden, Italy and Australia. — Elizabeth Jones

OGD, from Page 5

- Updated COA for the ingredient, including solvent identity, acceptance criteria and analytical method (loss on drying would be acceptable if only a Class 3 solvent is used in the manufacture of an ingredient);

- Test data for solvents, including data for Class 3 solvents;
- Method verification data for USP method and method validation data if non-USP methods are used;
- Demonstration that the ingredient meets <467> option 1 or option 2;
- An updated, finished-product specification stating compliance (including the option used); and
- Suitable qualification information to support residual solvents that are not defined as being Class 1, 2 or 3 solvents and are present at exposure levels greater than 1.5 micrograms per day.

For nonfunctional coating materials, colorants and flavors, testing of residual solvents present in any ingredient of the component is not necessary. — Elizabeth Jones

FazaClo, from Page 9

completely rewritten and narrowed, this could also significantly impact the Barr case," according to Chad Landmon of Axinn, Veltrop & Harkrider LLP.

However, if the Board of Patent Appeals and Interferences rules in favor of Cima, the patents themselves can, in essence, become stronger if the prior art that will be used in litigation to invalidate the patents is considered by the PTO. There is then a presumption that the patents are valid over that prior art.

Furthermore, there is a possibility the case could be stayed because of the pending reexaminations. — Elizabeth Jones

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